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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/797,363

03/10/2004

Jon S. Wilson

3600/289

4343

7590

01/27/2009

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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

01/27/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/797,363	<b>Applicant(s)</b> WILSON ET AL.	
	<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/14/09.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/6/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

### *Response to Amendment*

Amendment filed on 10/14/08 has been entered.

Claims 32-61 are present for examination.

Claims 1-31 are cancelled.

### *Terminal Disclaimer*

The terminal disclaimer filed on 10/14/08 disclaiming the terminal portion of any patent granted on this application has been reviewed and is accepted. The terminal disclaimer has been recorded.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Schweikert et al. (US 6,719,749).

*As noted that, Applicant defines the term "proximal" referred to those portions of a catheter inserted into an area of a patient's body such as a blood vessel; and the term "distal" for connection to a fluid exchange device, such as a dialysis machine or the like (Specification on page 11, lines 7-15). Meanwhile, Schweikert discloses opposite way. For example: the proximal portion 26, 30 referred as portions of a catheter inserted into the blood vessel, and the distal portions 10 of catheters referred as portions of catheter that outwardly from the patient's body.*

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Schweikert discloses a multi-lumen catheter comprising

(a) a one-piece multi-tube portion 20 having a plurality of integrally formed lumens 20, 23, the multi-lumen tube portion having a proximal end 10, distal end (opposite end with element 10, about portion of 11, 12);

(b) a distal portion 10 comprising a plurality of distal single-lumen tubes 38, 39; each proximal single lumen tube having a proximal end 42, 43 or 45 and a distal end (connected to element 48), the proximal end 42, 43 or 45 of each distal single lumen tube being permanently and directly connected to the distal end 10 of the multi-lumen tube portion such as the lumen of each distal single lumen tube 38, 39 is in fluid communication with one of the plurality of lumens of the multi-lumen tube portion (col. 8, lines 36-51, col. 12, lines 27-40).

(c) a proximal portion comprising a plurality of single lumen tubes 26, 30, each proximal single lumen tube 26, 30 having a distal end (portions of 34, 40) and a proximal end 26a, 30a, the distal end of each proximal single lumen tube being permanently and directly connected to the proximal end of the multi-lumen tube portion such that the lumen of each proximal single lumen tube is in fluid communication with one of the plurality of lumens of the multi-lumen tube portion; and

A plurality of extension members 52 configured at a proximal end thereof to be selectively attachable to one of the distal single lumen tubes 38, 39 and configured at a distal end thereof for connection to a fluid exchange device after reverse tunneling of the catheter tube within a patient.

*As noted that the recitation "after reverse tunneling of the catheter tube within a patient" is a method step in the device claim. Therefore, it is considered as a functional limitation.*

a connector 50 or 58; the connector further comprises means for attaching the connector to a trocar (col. 15, lines 4-44); the single-lumen tubes comprised of a fusible material (col. 9, line 36-col. 10, line 16); a stabilizing cuff 44; each extension member 38, 39 comprises a matting compression fitting and a tube portion (Fig. 1, col. 8, line 62, col. 9, line 25).

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### ***Response to Arguments***

Applicant's arguments filed 10/14/08 have been fully considered but they are not persuasive.

1. Applicant argues that Schweikert does not disclose "the proximal end of each distal single-lumen tube being permanently and directly connected to the distal end of the multi-lumen tube portion.

In response, Schweikert clearly discloses that the proximal end 42, 43 or 45 of each distal single-lumen tube 38, 39 being permanently (by heat molding, col. 8, lines 35-50) and directly connected to the distal end (portion connected to elements 48) of the multi-lumen tube portion.

Application acknowledge that the permanently connected (e.g. sealably fused together by heat welding or the like), see Remark, page 14, lines 5-6 filed on 10/14/08. Schweikert using heat molding to permanent attaches the proximal end of each distal single lumen tube with distal end of the multi-lumen tube portion.

2. Applicant argues that Schweikert can not be inserted into a patient through the reverse tunneling technique described in the present application because the hub can not be passed through a subcutaneous tunnel.

In response, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e....for connection to a fluid exchange device after reverse tunneling of the catheter tube within a patient, a functional limitation and method limitation in to structure device claim. Therefore, it does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974)

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763